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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,194	10/28/2003	Denis Francois Hochstrasser	A36054-PCT-USA-A 072874:0	4418
38485	7590	10/26/2005	EXAMINER SWARTZ, RODNEY P	
ARENT FOX PLLC 1675 BROADWAY NEW YORK, NY 10019			ART UNIT 1645	PAPER NUMBER

DATE MAILED: 10/26/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/695,194

Applicant(s)

HOCHSTRASSER ET AL.

Examiner

Rodney P. Swartz, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 09 August 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 20,23-28 and 47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-19,21,22 and 29-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 8-9-05 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

1. Applicants' Response to Office Action, received 9 August 2005, is acknowledged. Claims 1, 21, 29, 32-37, 40, and 43 have been amended.

Claims 1-47 are pending. Claims 20, 23-28 and 47 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention.

2. Claims 1-19, 21-22, and 29-46 solely drawn to method and kit for diagnosis of TSE using polypeptide are under consideration.

### **Rejections/Objections Withdrawn**

3. The objection to the figures for the type of designation is withdrawn in light of the amendments of the drawings and specification.

### **Rejections Maintained**

4. The rejection of claim 1-10, 16, 19, 21, 22, 37, and 39 under 35 U.S.C. 112, first paragraph, scope of enablement for utilizing any/all other body fluids or utilizing any other component having a molecular weight in the range of 1000-100000, is

Applicants argue that the amendment of the claims to recite a molecular weight in the range of from 1,010-31,800 obviates the rejection. In addition, applicants argue that the specification combined with knowledge of those skilled in the art fully supports utilizing body fluid taken from a subject, e.g., csf, blood, blood fractions, and urine.

The examiner has considered applicants' argument concerning molecular range, and finds that part of the rejection argument persuasive.

The examiner has considered applicants' argument concerning identity of the markers as polypeptides, but does not find it persuasive. As stated in the original rejection, the

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specification teaches only two possible markers, cystatin C and isoforms of hemoglobin. The specification does not teach that any other markers are differentially present in TSE disease.

The examiner has considered applicants' argument concerning utilizing any/all other types of bodily fluids, but does not find it persuasive for the reasons of record. The specification teaches only two fluids, CSF and plasma, and provides no evidence that the differential presence of cystatin C and isoforms of hemoglobin in TSE subjects exists in any other bodily fluid.

5. The rejection of claims 1-19, 21, 22, and 29-46 under 35 U.S.C. 112, second paragraph, indefiniteness for "determining whether the test amount is consistent with a diagnosis of TSE", is maintained for reasons of record.

Applicants argue that the amendment of the claims obviate the rejection.

The examiner has considered applicants' argument, but does not find it persuasive. Even after the amendments, the claims remain drawn to a method of diagnosis of TSE by determining whether the test amount is consistent with a diagnosis of TSE. Thus, *a priori*, the claims require that a diagnosis of TSE has been determined prior to the determination of the presence/absence of a polypeptide and comparison to some unknown test amount of polypeptide.

6. The rejection of claims 1-19, 21, 22, and 29-46 under 35 U.S.C. 112, second paragraph, indefiniteness for all other components in samples, is maintained for reasons of record.

Applicants argue that the claims clearly state that the molecular weights refer to polypeptides.

The examiner has considered applicants' argument, but does not find it persuasive. The claims remain indefinite concerning the identity of a substance whose only determination is that

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it has a molecular weight between 1010-31-800 daltons. While the instant claims may be drawn to determining the amount of a polypeptide, how does one determine if the substance is actually a polypeptide if the only characteristic is that a mass spectrometry indicates a molecular weight?

### Conclusion

7. No claims are allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. This application contains claims 20, 23-28, and 47 drawn to a nonelected invention. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.


10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 5:30 AM to 4:00 PM EST.

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If attempts to reach the Examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F. Smith, can be reached on (571)272-0864.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
RODNEY P. SWARTZ, PH.D.  
PRIMARY EXAMINER  
Art Unit 1645

October 21, 2005